

Remarks

New claims

Applicants have introduced new dependent claims 27-38. Applicants also introduced new independent claims 39 and 44. Claim 39 is directed to a method of inhibiting T-type calcium current in cells and claim 44 is a Jepson claim directed to the inhibition of T-type calcium current by a substance in a Hypericum perforatum extract other than hypericin. Claim 44, as well as somewhat related claim 42, are supported by Example 3.

Rejection under 35 U.S.C. §112, second paragraph

On page 2 of the Office Action, the Office rejects claims 8 and 25 under 35 U.S.C. §112, second paragraph as duplicative.

In response, Applicants have canceled claim 25.

Rejection under 35 U.S.C. §102 (b) or (e)

On pages 2 and 3, the Office rejects claims 1, 8, 10, 23, 25 under 35 U.S.C. §102 (b) or (e) as being anticipated by Khwaja et al. or Meruelo et al.

In particular, the Office alleges that Khwaja teaches the use of St. John's Wort (Hypericum perforatum) to treat the claimed diseases. The Office refers to the abstract, cols. 10, 20, 23-24, 27-28, etc. of the reference.

The Office further alleges that Meruleo teaches the administration of St. John's Wort

(Hypericum perforatum) to treat diabetes mellitus. The Office refers to col. 4 and 6.

In response, Applicants have amended the claim 1 to exclude diabetes mellitus. However, the Office is directed to Applicants' discussion of these references below, which will clarify the extent to which Applicants disagree with the Office's analysis of the references, in particular with the Office's analysis of Khwaja.

Rejection under 35 U.S.C. §103

On pages 3 and 4, the Office rejects claims 1, 8, 10, 23, 25 under 35 U.S.C. §103 as being obvious over Khwaja et al. or Meruelo et al.

The Office refers to its analysis of the references under the novelty rejection. Applicants submit that the references do not render the invention obvious for the reasons stated below.

Khwaja reference

Applicants submit that Khwaja does not teach the treatment of any of the diseases recited in the claims. Khwaja discloses the production of pharmaceutical grade Hypericum material. Khwaja also discloses known uses of Hypericum material, in particular of hypericin (col. 4-8). The patent discloses a number of assays that can be used for testing substances for consistent quality and suitability as a therapeutic agent. In a general description of the applicability of these assays, the patent lists diseases, including, e.g., cardiac arrhythmia. However, the patent does not teach nor purports to

teach the treatment of these diseases with Hypericum material as it does not tie Hypericum perforatum to the diseases currently listed in the present claims. At best, which Applicants deny, it would be obvious to try using an extract of Hypericum perforatum for the indicated diseases. However, "obvious to try" is not a recognized standard of obviousness (see MPEP §2145 X. B.).

With regard to the Meruelo reference, Applicants submit that no prima facie case of obviousness for the claims as amended has been established, as the motivation to modify the reference to arrive at the diseases listed in claim 1 is lacking.

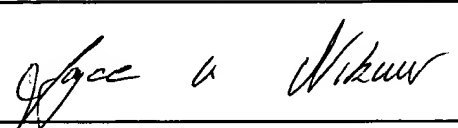
Also, Hypericum perforatum has been literally known for thousands of years. E.g., Hippocrates has been reported to have used it. Nonetheless, the Office was not able to produce art that specifies the diseases currently claimed. This fact strongly contradicts that the claimed invention is obvious.

The Office also rejects the claims over Meruelo and Khwaja in view of U.S. Patent No. 5,288,485 and 5,433,957, both to Kikuta et al.

Applicants submit that Kikuta et al. do not compensate for the above indicated deficiencies of the primary references. Again, Hypericum perforatum was known for a long period of time without anyone recognizing its use for the claimed ailments. As noted above, this strongly supports the non-obviousness of the presently claimed invention.

At the bottom of page 3, the Office appears to argue that the presentation of the conditions recited in claim 1 in form of a "Markush group" constitutes an admission by applicant that the treatment of one condition in the group would render the treatment of the other condition in the group obvious. Applicants submit that there is no foundation for this argument. This fact is evidenced, among others, by the PTO practice that applicant is allowed to remove members from Markush groups that were found to be part of the prior art and obtain allowance of the so amended claim. See also MPEP §2144.06.

In the event that this paper is not accompanied by the full fee required for its consideration, the Commissioner is authorized to charge any insufficient or missing fees to RFEM's deposit account No. 02-2135. The Commissioner is also authorized to deposit any overpayment to the same account.

RESPECTFULLY SUBMITTED,			
NAME AND REG. NUMBER	Joyce von Natzmer, Reg. No. 48,120		
SIGNATURE		DATE	1/30/04
Address	Rothwell, Figg, Ernst & Manbeck 1425 K Street, N.W., Suite 800		
City	Washington	State	D.C.
Country	U.S.A.	Telep hone	202-783-6040